AMENDMENTS TO THE SPECIFICATION

Amendments to the Drawings

The Applicant has provided replacement drawings for Figure 6. We have provided a marked-up version and a clean version. Please note that the only change to Figure 6 has been to replace, in box (114) the words "reverse thermal gradient produced" with "Volume of tissue beneath surface is heated." No other changes have been made to Figure 6.

Amendments to the Abstract

The following is a replacement abstract:

A system **30** and method(s) **100** for thermal treatment of a selected target within a subject is disclosed. System **30** includes RF source **10,** phase shifter **14,** impedance matching network **11** and resonator **13.** ~~Applicator 3 conveys output signal 17 from energy source 10 through surface 6 of biological tissue 4 to predetermined energy dissipation zone 5 after output 17 has been processed by the phase shifter 14, IMN 11 and resonator 13.~~ Stationary water molecules **1**, such as those in fat cells, are ~~preferentially~~ heated. ~~Operation of system 30 produces a reverse thermal gradient so that surface 6 of biological tissue 4 is maintained at a lower temperature than predetermined energy dissipation zone 5 without a cooling device.~~ The invention is useful in selective heating of cellulite bodies as a means of treating cellulite.

Amendments to Delete Paragraphs

1) Please delete from the specification paragraph [0006] the text of which is:

"Previously available alternatives are characterized by disadvantages which are obviated by the present invention."

2) Please delete from the specification paragraph [0084] the text of which is:

"Organization of energy dissipation inside of subcutaneous tissue insures maintenance of a relatively low temperature on the skin surface (epidermis). This provides a reverse thermal gradient without use of an external cooling system.

3) Please delete from the specification paragraph [0097] the text of which is:

It is an inherent advantage of system 30 that its operation produces a reverse thermal gradient so that surface 6 of biological tissue 4 is maintained at a lower temperature than predetermined energy dissipation zone 5 without use of a cooling device.

4) Please delete from the specification paragraph [0122] the text of which is:

Performance of 102, 104, 105, 108, 110 and 112 produce 114 a reverse thermal gradient so that surface 6 of biological tissue 4 is maintained at a lower temperature than predetermined energy dissipation zone 5, thereby obviating the need for a cooling device.

5) Please delete from the specification paragraph [0135] the text of which is:

It is an advantage of the present invention that epidermal layer 6 is heated much less than subcutaneous tissue 4. An inverse thermal gradient that is provided by intensive cooling of epidermis that described by Thermage patents is achieved automatically with deep heating of tissues.

The following is a listing of the replacement paragraphs for the specification including amendments currently entered as highlighted. The paragraphs are numbered as in the published patent application US 2007/0106349 and NOT according to the paragraph numbering in the physical application as filed.

REPLACEMENT PARAGRAPHS FROM THE "FIELD AND BACKGROUND" SECTION:

[0001] The present invention relates to an improved system and method for heating biological tissue via RF energy and, more particularly, to a system and method which rely upon a single electrode. Control of phase and pulse width modulation of applied RF waves ~~obviate the need for cooling of the skin surface while facilitating~~ facilitate efficient heating of underlying layers of tissue such as dermis and subcutaneous layers. Specifically, heating and contraction of adipose tissues as a means of cellulite reduction is achieved.

[0003] Previously proposed methods for cellulite treatment include Topical treatment, Teas and capsules, Cellulite wraps, Endermologie, Mesotherapy, Acthyderm and Ultrasonic and particularly focused ultrasonic treatment. These techniques have ~~not~~ demonstrated various degrees of clinical efficacy in reducing the "lumpy" appearance associated with cellulite deposits.

[0004] In addition, thermotherapy using electromagnetic radiation or radio-frequency (RF) waves has been proposed. RF treatment is more effective than other available therapy regimens since it permits the body to heal itself. ~~However, previously available thermotherapy solutions share, as an inherent disadvantage, a tendency to heat the skin to the point of causing a burn when sufficient RF energy is applied to heat the fat cell target in the deepest skin layer.~~ Non-invasive electromagnetic radiation, including radio-frequency waves, has been proposed in the prior art for treatment of fat and cellulite in addition to use for contraction of collagen, such as involved in the treatment of wrinkles.

[0005] The ~~currently accepted~~typical RF technique for heating of biological tissues involves exposing the tissue to RF voltage, which produces RF conductive current through the tissue at a level sufficient to overcome the tissue resistance. The current heats the tissue. This method causes uneven heat accompanied by burning of the outer layer(s) the skin. As a result, many of the conventional systems for implementation of this method share, as an inherent disadvantage, a strict requirement for a cooling mechanism to remove an excessive heat of the skin during the treatment.

[0007] One example of a prior art system(s) is disclosed in US Patent No. 6,662,054 assigned to Syneron Medical Ltd. This patent teaches deforming the skin so that a region of skin protrudes from the surrounding skin, and applying RF energy to the protruded skin. The system includes one or more RF electrodes, configured to apply conducted RF current to the skin, and a skin deformer, so that a region of skin protrudes out from surrounding skin and is exposed to the conducted RF current, which follows the deforming act. Teachings of this patent ~~have, as an inherent disadvantage,~~ include a strict requirement for cooling of the skin to prevent burning.

[0008] ~~Additional examples of prior art systems which require cooling of the skin to prevent burning include those disclosed in~~ US Patent Application No. 20040002705 assigned to Thermage, Inc. also discloses a system that requires cooling of skin to prevent burning. In particular, this published patent application teaches ~~which teaches~~ a method of creating a tissue effect by delivering electromagnetic energy through a skin surface from an electromagnetic energy delivery device coupled to an electromagnetic energy source. ~~At least one of the electromagnetic energy delivery device or electromagnetic energy source includes a memory. A reverse thermal gradient is created through the skin surface to sufficiently heat an underlying tissue site to provide that the temperature of the skin surface is lower than the temperature of the underlying tissue. The reverse thermal gradient is established by use of a cooling system, which is an inherent disadvantage~~.

[0009] Further additional examples of prior art systems which require cooling of the skin to prevent burning include those disclosed in US Patent Application No. 2004030332 and US Patent No. 5919219 assigned to Thermage, Inc., which teach a system and method for providing treatment to a skin surface by applying RF energy through the skin using a memory for gathering information. These systems include~~, as an inherent disadvantage,~~ express ~~a strict~~ requirements for a cooling lumen for receiving cooling fluid and a number of RF electrodes. The RF electrodes are provided to transfer RF current to the skin and are configured to be capacitive coupled to the skin surface, thus creating a heating effect through RF conducted current.

[0010] In summary, ~~all previously available~~the above-described prior art ~~-~~methods require the use of a separate cooling system to cool the outer skin layer throughout the RF treatment. Further, many of the previously available solutions require a memory unit to store local information pertaining to the treated area throughout the treatment. Further, many of the previously available solutions require extensive preliminary adjustments, such as local impedance matching, prior to each treatment. Further, despite use of the phrase "one or more electrodes in many prior art documents, ~~all previously available~~ the above-described alternatives share~~, as an inherent disadvantage,~~ a strict requirement for a return electrode pad to be placed against the patient to receive the RF currents after passing tissue being treated. This return electrode for volumetric treatment of adipose tissue (e.g. cellulite) routes a majority of energy through blood and lymphatic vessels. Fat cells are heated only by heat dissipated from these non-target tissues as a result of their inherent resistance.

[0011] There is thus a widely recognized need for, and it would be highly advantageous to have, an improved system and method for heating biological tissue via RF energy ~~devoid~~

~~of the above limitation(s)~~that atttempts to address one or more of the limitations of the above-described systems.

REPLACEMENT PARAGRAPHS FROM THE "SUMMARY OF THE INVENTION" SECTION:

[0043] According to one aspect of the present invention there is provided an improved system for thermal treatment of a selected target within a subject, the system includes: (a) an RF energy source capable of producing an output RF power signal directed to an applicator contactable with a surface of a biological tissue belonging to the subject, the applicator capable of delivering a desired amount of energy to a predetermined energy dissipation zone beneath the surface of the biological tissue, the selected target positioned within the predetermined energy dissipation zone; (b) a phase shifter, the phase shifter capable of shifting a phase of directed traveling waves of the output signal so that energy therefrom is concentrated primarily in the predetermined energy dissipation zone, which lies at a desired depth beneath the surface of the biological tissue; (c) an impedance matching network (IMN), the IMN capable of converting the impedance of the biological tissue belonging to the subject from a nominal value to a corrected value, *the corrected value* matching an impedance characteristic of the RF transmission line so that the directed traveling wave may pass through the surface of the biological tissue without being converted to a standing wave; (d) an RF resonator located in the applicator, the RF resonator capable of cyclically accumulating and releasing the desired amount of energy, the RF resonator further capable of concentrating the desired amount of energy so that a significant portion thereof is concentrated in the predetermined energy dissipation zone; and (e) the applicator capable of conveying the output RF power signal from the RF energy source through the surface of the biological tissue to the predetermined energy dissipation zone after the output has been processed by the phase shifter, the IMN and the resonator. ~~Operation of the system produces a reverse thermal gradient so that the surface of the biological tissue is maintained at a lower temperature than the predetermined energy.~~ The

absence of a ground electrode permits free propagation of the waves of the output RF power signal in the energy dissipation zone.

[0044] According to another aspect of the present invention there is provided an improved method for thermal treatment of a selected target within a subject. The method includes: (a) providing an output RF power signal directed to an applicator contactable with a surface of a biological tissue belonging to the subject, (b) employing a phase shifter to shift a phase of directed traveling waves of the output RF power so that energy therefrom is concentrated primarily in a predetermined energy dissipation zone which lies at a desired depth beneath the surface of the biological tissue, wherein the selected target is positioned within the predetermined energy dissipation zone; (c) converting the impedance of the biological tissue belonging to the subject from a nominal value to a corrected value, the corrected value matching an impedance characteristic of RF-transmission line so that the directed traveling wave may pass through the surface of the biological tissue without being converted to a standing wave by means of an impedance matching network (IMN); (d) cyclically accumulating in an RF resonator located in the applicator, and releasing therefrom, the desired amount of energy, (e) concentrating the desired amount of energy in the RF resonator so that a significant portion thereof is concentrated in the predetermined energy dissipation zone upon release therefrom; and (f) conveying the output signal of RF energy through the surface of the biological tissue to the predetermined energy dissipation zone after the output has been processed by the phase shifter, the IMN and the resonator by means of the applicator. ~~Performance of (a) - (f) produces a reverse thermal gradient so that the surface of the biological tissue is maintained at a lower temperature than the predetermined energy dissipation zone, thereby obviating the need for a cooling device.~~ The absence of a ground electrode permits free propagation of the waves in the output signal in the energy dissipation zone.

[0045] According to yet another aspect of the present invention there is provided an improved method for cellulite treatment. The method includes: (a) providing an output signal of RF energy directable to an applicator contactable with a surface of a biological tissue belonging to the subject, (b) employing a phase shifter to shift a phase of directed traveling waves of the output RF power so that energy therefrom is concentrated primarily in a predetermined energy dissipation zone which lies at a desired depth beneath the surface of the biological tissue, wherein the selected target is positioned within the predetermined energy dissipation zone, the predetermined energy dissipation zone including at least one cellulite body; (c) converting the impedance of the biological tissue belonging to the subject from a nominal value to a corrected value, the corrected value matching an impedance characteristic of RF-transmission line so that the directed traveling wave so that the output signal may pass through the surface of the biological tissue without being converted to a standing wave by means of an impedance matching network (IMN); (d) cyclically accumulating in an RF resonator located in the applicator, and releasing therefrom, the desired amount of energy, (e) concentrating the desired amount of energy in the RF resonator so that a significant portion thereof is concentrated in the predetermined energy dissipation zone upon release therefrom; and(f) conveying the output power from the RF energy source through the surface of the biological tissue to the predetermined energy dissipation zone after the output has been processed by the phase shifter, the IMN and the resonator by means of the applicator. ~~Performance of (a) - (f) produces a reverse thermal gradient so that the surface of the biological tissue is maintained at a lower temperature than the predetermined energy dissipation zone, thereby obviating the need for a cooling device.~~ The absence of a ground electrode permits free propagation of the waves in the output signal in the energy dissipation zone. The at least one cellulite body is heated to a greater degree than a tissue adjacent thereto.

REPLACEMENT PARAGRAPHS FROM THE "BRIEF DESCRIPTION OF PREFERRED EMBODIMENTS" SECTION:

[0083] Phase shifting techniques provide the possibility of concentration of RF-energy at a predetermined location ~~depth with respect to the skin surface~~ by variation of position of RF-wave maximum

[0100] The inherent advantages of system **30** are clear from comparison of thermo-grams of energy dissipation zone **5** using system **30** (Figure 4) and a prior art bipolar (i.e. 2 electrode) system (Figure 5). Each thermo-gram is accompanied by a key on the left which indicates that the colors white, yellow, orange, red, green, blue and violet represent concentrations of heat energy in decreasing order. In each figure, an apple slice is used as biological tissue 4. ~~Specifically, it is clear that system 30 moves zone 4 away from surface 6 of tissue 4.~~

[0101] Figure 4 clearly shows that when applicator **3** of system **30** is contacted **with** surface **6** of tissue **4**, delivery of output energy **17** results in delivery of energy primarily to zone **5**. Line **26** passes through the center of zone **5**. ~~The temperature at surface 6 of tissue 4 is clearly lower than along line 26 in zone 5. In other words, operation of system 30 creates a reverse thermal gradient and obviates the need for a cooling system to prevent undesired overheating of surface 6.~~

[0102] In sharp contrast, Figure 5 clearly shows that when applicator **3** of a prior art bipolar system is contacted with surface **6** of tissue **4**, delivery of output energy **17** results in delivery of energy primarily to a zone **5** which is adjacent to surface **6** of tissue **4**. This reduces the distance between line **26**, which passes through the center of zone **5**, and surface **6**. In other words, the prior art bipolar system delivers heat energy primarily in proximity to surface **6**. The thermo-gram of Figure 5 illustrates a distribution of heat energy observed when the prior art bipolar system is operated with a cooling system. ~~Despite this cooling system, no reverse thermal gradient is achieved.~~

[0131] Preferably, applicator **3** is constructed from aluminum or an aluminum alloy covered by alumina coating with a thickness 40-50 μm. ~~Applicator 3 serves also to cool tissue surface 6, thereby obviating the need for a separate cooling system~~.

[0134] The applied oscillating RF-field stimulates all dipole molecules (mostly water molecules **1**) to rotate and vibrate with consequent heating of energy dissipation zone **5**.

Zone **5** may be controlled by phase shifting device **14** between RF-generator **10** and applicator **3**. Heating will be primarily in adipose tissue because it is rich in liquids but not subject to convective cooling as blood vessels are. ~~Thus, collagen capsules will be destroyed by heating because their high thermo isolation.~~ The pulse width modulation (PWM) control **12** of output RF- power that provide a possibility to keep a high peak RF-power with low average power level ~~will leads to the most efficient collagen capsule destruction.~~

[0144] In order to reach necessary amplitude under the surface **6** of tissue **4**, a phase shifting system (e.g. trombone-type system **14**) is inserted between output of RF-generator **10** and an input of IMN **11**. The position of the maximum of energy dissipation can be controlled by this phase shifting system ~~and can be placed under surface 6 of tissue 4.~~ In order to control the depth of RF-energy penetration the length of trombone can be shortened that change a position of dissipated electromagnetic wave in the tissue or an area of the maximum of RF-voltage. Consequently, RF-energy will be dissipated most efficiently in the volume around maximum of the RF-voltage.